EXHIBIT
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METHOD AND DEVICE FOR FEEDING COMPONENTS FOR BONE CEMENT INTO A MIXING VESSEL FOR THESE

#24

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method for successively feeding batches of constituent components into a mixing vessel for the preparation of bone cement under vacuum. The invention also relates to an apparatus for successively feeding batches of constituent components into a mixing vessel under partial vacuum for the preparation of bone cement.

2. Description of the Prior Art

Bone cement is prepared by mixing polymethyl methacrylate in powder form, with liquid monomethyl methacrylate in a mixing container. Both the liquid component and the combined mixture give off substances in gaseous form which are environmentally harmful and injurious to human health. For this reason, it is important for the introduction of the bone cement components into the mixing container and the mixing process itself, to take place in such a way that the smallest possible quantity of the harmful gases escape into the surrounding environment. Mixing vessels in which the introduced components were successfully prepared into bone cement without a substantial release of the aforementioned gases are described in SE-C-8901599-4 and SE-A0-9201353-1, for example. In order for the bone cement to develop optimal strength during use, it is also important for the components comprising the cement to have well-mixed, predetermined proportions.

SUMMARY OF THE INVENTION

The object of the present invention is to make available a method of the kind described above, which avoids the risk of gas release when feeding the bone cement components into the mixing vessel. This is achieved in accordance with the invention in that according to the method, a glass ampoule containing a liquid component of a bone cement is surrounded by a container which is in reclosable communication with the atmosphere. A second container surrounds the first container so that when the mixing vessel is opened, the contents of the ampoule, under the effect of a partial vacuum inside the mixing vessel, can be sucked down into it, in that a space formed by the spaces between the aforementioned inner container and by the outer container that encloses it at least partially and filled with a bone cement component in powder form is caused by displacement of the inner container relative to the outer container to move from a first position in which the space does not communicate with the atmosphere or the mixing vessel to a second position in which it communicates with the atmosphere and the mixing vessel, so that the bone cement component in powder form can be sucked down into the mixing vessel under the effect of the partial vacuum inside it.

A device for carrying out the method in accordance with the invention is characterized in that it comprises, on the one hand, an inner container communicating with the atmosphere, which is so arranged as to enclose a glass ampoule containing a liquid bone cement component, and so as to communicate with the aforementioned mixing vessel, and comprising means for opening the ampoule so that its contents, under the effect of the partial vacuum inside the mixing vessel, can be sucked into it. An outer container at least partially enclosing the inner container is so arranged so as to communicate with the mixing vessel and together with the inner container, defines a space filled with a certain quantity of the powdered component of the bone cement. The inner container is capable of

displacement from a first position to a second position, the first position characterized by the inner container preventing communication between both the mixing vessel and the atmosphere, and the second position characterized, in which communication between the mixing vessel on the one hand and the atmosphere on the other hand is open, so that the bone cement component in powder form, under the effect of the partial vacuum inside the mixing vessel, can be sucked into it without escape of gases.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described below in greater detail with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view in longitudinal section of an embodiment of a feeding/mixing device of the present invention with the mixing vessel filled with bone cement components in liquid and powder form, prior to mixing;

Figure 2 illustrates the feeding of the liquid bone cement component into the mixing vessel;

Figure 3 illustrates the feeding of the powder bone cement component into the mixing vessel;

Figure 4 illustrates a second embodiment of the invention in longitudinal cross-section;

Figure 5 illustrates feeding the liquid bone cement component into the mixing vessel of Figure 4;

Figure 6 illustrates a third embodiment of the present invention where feeding the powder component into the mixing vessel differs slightly from that of Figure 4;

Figure 7 illustrates the mixing vessel of a fourth embodiment of the present invention in which the powder form of the bone cement pre-exists within the mixing vessel;

Figure 8 illustrates a container and a cassette that houses a glass ampoule which contains the liquid form of the bone cement;

Figure 9 illustrates a cross-sectional view of the mixing vessel of Figure 7 prior to mixing the cement components;

Figure 10 illustrates the mixing vessel of Figure 9, feeding the liquid into the vessel;

Figure 11 illustrates the mixing vessel of Figure 7 with the bone cement components thoroughly mixed;

Figure 12 illustrates the mixing vessel of a fifth embodiment of the present invention in which the liquid form of the bone cement is fed into the mixing vessel through the side wall;

Figure 13 illustrates the mixing vessel of a sixth embodiment of the present invention where the liquid bore cement component is contained in a collapsible plastic bag.

DETAILED DESCRIPTION OF THE INVENTION

The designations 1 and 2 are used generally in the drawings in respect of a feed arrangement and a mixing vessel. The latter comprises an interior 2a, a cylindrical container 3 comprised of an outer cylinder wall 3a, a bottom 4 at one end of the container and a spout 5 with a sealed opening at the other end, together with an agitator 6, received within said spout and mixing vessel and capable of axial, vertical movement inside the container 3. The agitator 6 consists of an agitator disc 6a attached to a tubular agitator rod 6b. The agitator 6 is mounted so that it is free to vertically slide up and down while maintaining a seal in the spout 5, in such a way that the plurality of holes 6h in agitator disk 6a can be used to bring about through mixing of the bone cement components within mixing vessel 2 with no gaseous escape to atmosphere. Once mixing is complete, and once a lock 7 has been removed, the bottom 4 can be axially displaced inside the cylinder by upward movement of piston head 80, moving towards the spout 5. The piston-like

function of bottom 4, upwardly pushes and then discharges the mixed bone cement via the hollow agitator rod 6b, which now serves as a discharge nozzle. The interior of the container 2 communicates via a filter 8 with a vacuum source (not shown) during feeding and mixing of the bone cement components. Rapid and effective feeding of the bone cement components into the mixing vessel, and safe handling of the gases that are environmentally harmful and injurious to human health, are achieved in this way.

The feeding of the bone cement components from the feed arrangement 1 into the mixing vessel 2 takes place via the agitator rod 6b, and the details concerning the component mixing within vessel 2 will be described later.

The feed arrangement 1 of the first embodiment, shown in Figures 1-3, comprises an inner, essentially cylindrical container 9 communicating with the atmosphere and an outer, similar cylindrical container 10 which at least partially encloses the inner container. The container interior 9e is so arranged so as to enclose a glass ampoule 11 containing the liquid bone cement component A, and to communicate with the mixing vessel 2, via its agitator rod 6b, as already mentioned. The container 9 is integrally formed having a cylindrical collar 12 about its bottom end 9b with a threadable cap 18 capable of axial displacement relative to it. Removal of cap 18 allows insertion of ampoule 11 within interior 9e.

In the embodiment illustrated in Figure 1, the facility for displacement to take place between the cylindrical collar 12 and the cap 18 is achieved by means of the internal collar threads 12a engaging the external cap threads 18a. The cap 18 has an opening 18d communicating between the interior 9e of the container 9 and the atmosphere, and the container 9 has a funnel-shaped top end 9a, with the narrow neck portion 9c having an outside diameter which frictionally inserts within, and discharges into the open agitator rod 6b. In the first embodiment in accordance with Figures 1-3, a tip 11a of the glass ampoule 11 points downwards, and there is present inside the interior 9e of container 9, a glass ampoule breaking means 13 in the form of an oblique plane 13a. Tip 11a of the glass ampoule 11, which has a fractural impression therein, rests against means 13.

The bottom 18b of the cap has an annular raised wall 18w, which contacts ampoule 11, thereby clamping it between means 13 and cap 18. When cap 18 is screwed axially downwards, the tip 11a is eventually broken off against the oblique plane 13a, and the contents of the ampoule are sucked downwardly through opening 13c of means 13, into the mixing vessel 2 by the partial vacuum existing inside of it, as illustrated in Figure 2. A filter 14 is provided for the purpose of preventing glass splinters from the glass ampoule 11 accompanying the contents into the mixing vessel 2. In the second and third embodiment in accordance with Figures 4-6, the tip 11a of the glass ampoule points upwards, and the inner container 9 has a glass breaking means 13 in the form of an upward-facing and pointed cone 13b, against which the bottom 11b of the glass ampoule rests. The bottom 18b of the cap 18 is formed with vertically taller walls 18w, such that they contact ampoule 11, thereby clamping it in place. When cap 18 is screwed downwards, the bottom 11b of the glass ampoule 11 is penetrated by the cone 13b and, as previously described for the first embodiment, the contents of the glass ampoule are sucked downwardly through openings 13c, then into the mixing vessel 2. A filter 14 can also be provided. As the liquid bone cement component of the glass ampoule 11 flows down into the mixing vessel 2, air is sucked in via the opening 18d thereby sealing and preventing the gases from the liquid bone cement component from escaping into the atmosphere.

The outer container 10 is generally similar in shape to the inner container 9, with container 9 being concentrically arranged within at least a part of container 10. Outer container 10 also has a top end formed as a funnel-shaped part 10a, with a reduced neck member 10c that has an inside diameter slightly larger than the outside diameter neck 9c of inner container 9 so that neck 9c is also frictionally contacting neck member 10c. The neck 10c has a flared end 10d which inserts over the open end of agitator rod 6b. A space 15 exists between containers 9 and 10, and the powder component B of the bone cement is to be received therebetween prior to mixing. The bottom 10b of container 10 has an outer surface 10e that is formed with threads 10t. Threads 10t are in threaded

engagement with the internal threads 16d on downwardly depending edge 16c of interlocking cap 16, thereby closing the top of container 10. The central throughbore 16e includes threads 16f for threadingly receiving inner container bottom collar 12. In this way, when inner container 9 is threaded downwardly be engaging threads 12t against throughbore threads 16f, grooved annular flange 12d is seated against annular seat 16h. At the same time, O-ring 17 creates a seal against the annular upstanding lip 16g. When in this first position, the outer container is sealed at its bottom end from the atmosphere. When inner container 9 is axially displaced within the interlocking cover 16, in an opposite direction, this seal is broken. Comparing Figures 2 and 3, it is seen that the inner container is now upwardly displaced in the axial direction wherein, the funnel-shaped tops 9a and 10a disengage each other and the containers no longer form a closure of the space 15 at the necks 9c and 10c. The inner container is raised until the threads 12t are run-out, so that container 9 now allows the space 15 to communicate with the inside 2a of the mixing vessel. In the latter position, channels 16j are now opened in communication with the atmosphere, facilitating the introduction of the powder component of the bone cement out of space 15 and into vessel 2, through the partial vacuum inside the mixing vessel, Air allowed into container 10 prevents the aforementioned gases from finding their way into the atmosphere.

The third embodiment in accordance with Figure 6, shows that the only difference between this embodiment and the embodiments of Figures 4 and 5, is found in the brush-shaped devices 9d which are arranged as to make contact with the surface of the funnel-shaped part 10a in the first position of container 9. The bone cement component B is released from the aforementioned surface by relative rotation between the outer and inner containers such that trushes 10d, under weight of the powder, collapse and allow powder to fall into tube 6b.

A feed procedure of the above-described embodiments will now be summarized below with reference to Figures 1-6 of the drawings. It should be understood that with these embodiments, the feed arrangement is supplied ready for use, meaning it is filled with the bone cement components in the correct

proportions.

As Figure 1 illustrates, in order to permit feeding of the bone cement components into the mixing vessel 2 from the feed arrangement 1 in accordance with the invention, the mixing vessel 2 is required to be connected to an active vacuum source. The pin 18c is first removed, and the displaceable cap 18 is screwed downwards, wherein the glass ampoule 11 is also caused to move downwards. Screwing continues until the tip 11a of the glass ampoule 11 is broken off against the breaking means plane 13a, (See Figure 2) or until the bottom 11b of the glass ampoule is penetrated by the tip of the cone 13b (See Figure 5). The liquid bone cement component now flows down into the mixing chamber 2 under the effect of the partial vacuum existing inside of it. Once the glass ampoule 11 is totally empty, the cylindrical collar 12 is rotated from the first and sealed position so that the inner container 9 is axially displaced upwards to the second position shown in Figure 3, in which the space 15, which was previously closed at its top and sealed from the atmosphere at its bottom, is now opened at the bottom, via the channels 16j, and at the neck 9c, 10c. The powder component B of the bone cement is now allowed to drop downwardly into mixing chamber 2. Once the space 15 has been completely emptied, the entire feed arrangement 1 is removed, and the inner tubular part 6b of the agitator rod 6 is sealed with a sealing rod 19 (shown in Figure 12) which seals the bottom second end 6e. The mixing procedure can now start.

The feed arrangement of the embodiments just described can be modified in many ways within the scope of the invention. This is true, for example, of the facility for axial displacement between the inner container 9 and its cap 18, and between the inner container 9 and the outer container 10, which facility for axial displacement can be achieved other than by threaded engagement. Also, means other than the oblique plane 13a or the pointed cone 13b can be considered for the purpose of breaking open the ampoule 11. Furthermore, the emptying sequence can also occur in the reverse order to that described above, i.e. first the powdered component of the bone cement can be dropped, and then the liquid

bone cement component.

Turning attention now to Figures 7-12, a fourth and a fifth embodiment of the present invention will now be described. These two embodiments differ from the previously described ones from the perspective that the powdered component of bone cement pre-exists within the mixing vessel 2 prior to any mixing procedures, and that the container 9 contains only the liquid component. It will become clearer after reading the following description that the main characteristic of the fourth embodiment is that only the liquid component will be drawn into the mixing vessel under vacuum like the previous embodiments, and that a slightly different ampoule arrangement is provided wherein the contents feed downward through the tubular agitator rod 6b, and enter vessel 2 in the vicinity of the vessel bottom 4. The fifth embodiment uses a similar ampoule arrangement, however, the ampoule does not rest on the mixing vessel and the contents enter through the outer cylindrical wall 3a, also near the mixing chamber bottom 4. The fourth and fifth embodiments, as well as the sixth one described later, are also provided with a second filter 21, located at the top of mixing vessel 2.

In accordance with the fourth embodiment, Figures 7-11 show mixing vessel 2 as being pre-filled with the powder component of the bone cement. A tightening rod 19 is received within tubular agitator rod 6b of agitator 6 and has plug 19a and O-ring 19c inserted within a groove 19b thereof, to form an air-tight seal so that powdered contents B are not contacted by and affected by atmospheric air which is capable of downwardly travelling along tubular rod 6b to vessel bottom 4. Just prior to introducing glass ampoule 11 on top of mixing vessel 2, tightening rod 19 is completely removed from tube 6b, wherein the cylindrical container 9 is placed on top of vessel 2 by inserting funnel-shaped neck 9c into mouth 6c at the first end 6d of tubular rod 6b. Although Figures 1-6 show funnel shaped top end 9a as having a slightly different contour from that of the same section shown in Figures 7-12, it should be understood that either contour can be used interchangeably in these embodiments. Figure 8 shows in greater detail that glass ampoule tip 11a is pointing upwards when inserted within container 9, and that the

ampoule is resting upon the upward cone 13b of breaking means 13, said means having internal passages 13c for allowing liquid there through once it passes filter 14. Figure 8 also illustrates that cap 18 is constructed slightly modified in that cap 18 has gripping means 18h for facilitating the operative threading movement of cap 18 along container threads 12a. Figure 9 shows the ampoule 11 just prior to being broken. Figure 10 shows that when handle 18h of the cap is turned so as to downwardly displace the cap 18 through action of the interacting threads 12a and 18a, shoulder 18s pushes downwardly against ampoule 11, causing upward-facing, pointed cone 13b to break bottom 11b of the ampoule, thereby allowing liquid contents A to flow through filter 14 under suction downwardly into hollow tube 6b as previously described. As Figure 10 shows, openings 18d and 18e in cap 18, allow atmospheric air to be communicated into the interior of container 9 under suction, also as previously described, thereby preventing noxious fumes escaping to atmosphere. A small gap 23 exists between vessel bottom 4 and agitator disk 6a so that as liquid A descends tubular rod 6b, exists open end 6e, then it enters gap 23, which behaves as a passage for percolating an air/liquid mixture upwardly through holes 61t in the agitator disk 6a, so that air bubbles cause liquid A to thoroughly mix with the powder component B, while under the continuing action of the vacuum source. Figure 11 illustrates that once ampoule 11 is empty, container 9 is removed and replaced with tightening rod 19. While still under vacuum, tubular rod 6b is grasped and then successively moved up and down in the direction of arrow 30 and down with rod 19 still inserted therein, as the outlined representation in Figure 11, so that agitator disk 6a ensures thorough mixing of the liquid and powder components, while rod 19 prevents gaseous escape from tubular rod 6b due to O-ring seal 19c. The filter 21 is provided to remove heavy particulate before it can be drawn into the vacuum source 8. Once admixed, lock 7 is removed and bottom 4 can be axially displaced within cylinder 3 in a fashion similar to a piston, as previously described, so that the mixed bone cement can be pushed out of vessel 2 once tightening rod 19 is removed. In this way, agitator rod 6 is pulled completely up so that agitator disk 6a contacts the top end 3b of

cylinder 3, with tubular rod 6b acting as a discharge nozzle for the now-ready cement.

Figure 12 shows a fifth embodiment of the present invention wherein the mixing vessel is again pre-filled with powder component B and where container 9 has top end 9a connected to a tube 26, shown as being inserted into hole 27 which penetrates cylinder wall 3a. It is to be understood that prior to insertion of tube 26, plug 121 is inserted within hole 27, thereby maintaining a seal from the atmosphere. When mixing is to proceed, plug 121 is removed and then the tube is inserted into hole 27. It is preferable that for any introduction of liquid material A through the vessel wall 3a, hole 27 should always be located as close as possible to the bottom 4 and piston head 80 in order to advantageously use the entire height of mixing vessel 2 to thoroughly mix components A and B. As previously described, as with Figure 10, mixing takes place under suction, with atmospheric air entering cap 18 and container 9. Once mixed, plug 121 is re-inserted into hole 27, lock 7 removed, and the contents pushed upwards with piston head 80 for eventual discharge out tube 66.

Figure 13 shows a sixth embodiment, where container 9 is now comprised of collapsible plastic bag, similar to those commonly used in hospital applications. This substitution advantageously reduces the cost to manufacture, and is less bothersome than breaking and discarding the glass ampoule bottles. Again, this arrangement functionally mixes the elements together as previously explained. However, as seen in Figure 13, a U-shaped sleeve member 29 is used as a valve, where tube 26 is folded and frictionally inserted within sleeve interior 29a, thereby blocking any flow of material A. Then, plug 121 is removed from cylinder wall 3a, and is inserted into hole 27. Figure 13 shows a coupling 30 being inserted into tube 26 to facilitate the connection into the cylinder wall and to allow discharge of fluid A more centrally within mixing vessel 2 once inserted through hole 27. It should be realized that the embodiments of Figures 6-12 could also be provided with coupling 30 if desired. Mixing is completed by upwardly and downwardly moving agitator disk 6a as previously described, using mouth 6c of rod

6b as a discharge nozzle once desk 6a is contacted against top end 3a of cylinder 3, and tightening rod 19 is removed so that the mixed contents can be pushed upwards by bottom 4.

What is claimed is:

1. A method for successively feeding in an arbitrary sequence batches of a liquid and a powder [constituent components] bone cement component into a mixing vessel under vacuum for the preparation of said bone cement [under vacuum], comprising the steps of: providing a mixing vessel having an open interior; [characterized in that, in an arbitrary sequence, a glass ampoule containing a liquid bone cement component surrounded by] providing an inner container which communicates [communicating] with the atmosphere at one end and with the mixing vessel at the other end; [is opened so that the contents of the ampoule, under the effect of the partial vacuum inside the mixing vessel, can be sucked down into it, in that] providing a second and outer container which at least partially surrounds said inner container, wherein a space is formed [by the spaces] between the [aforementioned] inner container and [by] the outer container; [that encloses it at least partially and filled with] providing a bone cement component in powder form [is caused by] in said space; providing a liquid component within said inner container;

causing upward axial displacement of the inner container relative to the outer container to move said inner container from a first position in which the space does not communicate with the atmosphere or the mixing vessel, to a second position in which [it] said space communicates with the atmosphere and the mixing vessel, so that the bone cement component in powder form can be [sucked] drawn down into the mixing vessel under the effect of the partial vacuum inside it and wherein said liquid component can be drawn down into said mixing vessel under said same vacuum in order to mix said components without allowing noxious fumes to escape to atmosphere from either container.

7. (Amended) The apparatus according to Claim [6] 8 wherein the inner container is provided with brush-like devices in contact with the funnel-shaped [part] end of the outer container [in the vicinity of its funnel-shaped

part] and so arranged so as to release the bone cement component in powder form from the funnel-shaped part.

8. An apparatus for successively feeding batches of a liquid and a powder component into an interior of a mixing vessel for preparation of a bone cement, said mixing vessel interior maintained under a vacuum created from a vacuum source, comprising:

a generally cylindrical inner container which is defined by a top, a bottom, and an interior, said inner container axially displaceable between a first and a second position, said bottom end in communication with said mixing vessel, while in said first position, and while in said second position, said top end axially displaced above said mixing vessel, no longer in communication therewith, said bottom end in communication with the atmosphere in both of said positions;

a generally outer container which is defined by a top, a bottom, an outside surface and an interior, said interior of said outer container concentrically receiving at least a portion of said inner container therein, thereby defining a space between said containers, said space being filled with said powdered component of said bone cement when said inner container is in said first position said outside surface near said bottom end of said outer container being threaded;

an interlocking cover connected to said bottom end of said outer container, said cover having a top and a bottom surface and a downwardly depending edge, said edge including a threaded internal surface for screwed engagement to said threads of said outer container, said cover including a threaded and centrally located throughbore which receives said inner container therethrough said throughbore and said interior of said outer container being sealed from communication with the atmosphere when said inner container is in said first position;

a glass ampoule having a sealed interior and a tip, said sealed interior containing said liquid bone cement component, said ampoule received within said interior of said inner container with said tip facing said inner container top end;

said bottom end of said inner container integrally formed with a cylindrical collar thereabout, said collar having a top portion of a defined extent and a bottom portion of another defined extent, said bottom portion having an

inside surface and an outside surface with said outside surface being threaded along said extent thereof, said top portion having an inside surface and an outside surface, said inside and outside surfaces of said top portion axially and integrally coextensive with said inside and outside surface of said bottom portion, said outside surface of said top portion including a grooved, annular flange at a first end of the top portion, said inside surface of said top portion being partially threaded at a second end, said grooved flange receiving an O-ring, wherein a rotation of said cylindrical collar in a first direction causes said O-ring to sealingly contact against said annular upstanding lip encircling said throughbore of said interlocking cover, said sealing contact of said O-ring occurring when said inner container is in said first position,

a cap having threads formed on an outside surface thereof, said cap threadably received within said bottom end of said inner container, said cap having an opening therein whereby atmospheric air is communicated through said cap and into said interior of said inner container, said inner and outer containers top ends which are funnel-shaped, with respective lower portions defined respective neck members, said funnel-ends concentrically arranged such that said inner container neck member is frictionally received within said neck of said outer container when said inner container is in said first position, said frictional contact creating a seal therebetween such that said powder component is prevented from discharging out of said outer container, said inner and outer container neck members simultaneously in communication with said mixing chamber,

wherein a rotation of said cylindrical collar in a second direction opposite to said first direction, causes a separation in the sealing contact between said inner and outer containers and allows atmospheric air into said interior of said outer container, said separation corresponding to said second axial position of said inner container, wherein said powder between said containers descends into said mixing chamber and said liquid component is released from said ampoule so that each of said components mix together while descending into said mixing vessel under the vacuum existing therein, each of said containers in communication with

said atmosphere while said inner container is in said second position such that no harmful emissions are released to the atmosphere.

--9. The apparatus of claim 8 wherein said interior of said inner container includes an ampoule breaking means and a filter immediately therebelow, said means including a plurality of internal passages for communicating said liquid component through said means after said ampoule is broken.--

--10. The apparatus of claim 9 wherein said interlocking collar includes an annular upstanding lip surrounding said throughbore and disposed away therefrom so as to form an annular seat between said lip and said throughbore.--

--11. The apparatus of claim 10 wherein said cylindrical collar includes a grooved, annular flange at a first end of said top portion thereof, and said inside surface of said top portion is partially threaded at a second end thereof, said annular groove receiving an O-ring therein, wherein said O-ring sealingly contacts against said annular upstanding lip of said interlocking cover and said annular flange contacts against said annular seat of said interlocking cover when said inner container is in said first position.--

--12. The apparatus of claim 11 rotation of said cylindrical collar in said second direction causes said annular flange to separate from said annular seat of said interlocking cover thereby separating said O-ring from said annular lip, said rotation continued until said neck member of said inner container is no longer contacting said neck member of said outer container.--

--13. An apparatus for successively feeding batches of a liquid and a powder component into an interior of a mixing vessel for preparation of a bone cement, said mixing vessel interior maintained under a vacuum created from a

vacuum source, comprising:

a mixing vessel pre-filled with a powder component of said bone cement, said vessel defined by an outer wall having a top end, a bottom end and an interior, said top end formed with a sealable spout, said bottom end formed with an axially displaceable bottom;

an agitator received within said vessel interior, said agitator comprised of a tubular inserted rod which extends upwardly out of said interior, through said spout, and an agitator disk attached to said tubular rod, an open, first end of said tubular rod defining a mouth and an open, second end of said tubular rod encircled by said disk, said tubular rod axially displaceable within said vessel interior for mixing said bone cement components;

a tightening rod disposed within said tubular rod for sealing said open bottom rod end from communication with the atmosphere;

a generally cylindrical container having a top, a bottom, and an interior, said inner container axially displaceable between a first and a second position, said bottom end in communication with said mixing vessel, while in said first position, and while in said second position, said top end axially displaced above said mixing vessel, no longer in communication therewith, said bottom end in communication with the atmosphere in both of said positions;

an glass ampoule having a sealed interior and a tip, said sealed interior containing said liquid bone cement component, said ampoule received within said interior of said inner container with said tip facing said inner container top end;

a cap having threads formed on an outside surface thereof, said cap threadably received within said bottom end of said inner container, said cap having an opening therein whereby atmospheric air is communicated through said cap and into said interior of said inner container, said inner and outer containers top ends which are funnel-shaped, with respective lower portions defined respective neck members, said funnel-ends concentrically arranged such that said inner container neck member is frictionally received within said neck of said outer

container when said inner container is in said first position, said frictional contact creating a seal therebetween such that said powder component is prevented from discharging out of said outer container, said inner and outer container neck members simultaneously in communication with said mixing chamber, said frictional contact creating a seal therebetween such that said powder component is prevented from discharging out of said outer container;

wherein said sealing rod is removed from said tubular and replaced with said container, said contents of said ampoule being downwardly fed into said tubular rod and entering said vessel interior near said bottom, as said liquid exits said open, second end, said leg and powder components mixing within said interior under vacuum, wherein air is communicated through said container and into said vessel through said tubular rod so that no harmful emissions escape to said atmosphere during mixing.--

--14. A method for successively feeding in an arbitrary sequence batches of a liquid and a powder bone cement component into a mixing vessel under vacuum for the preparation of said bone cement providing a mixing vessel with a pre-determined amount of said powder component of said cement

providing a mixing vessel which is defined by a cylindrical cylinder having an open interior, a spout attached to one end of said cylinder, and an axially displaceable bottom;

inserting a mixing agitator within said spout so as to communicate with said vessel interior, said agitator comprised of a tubular rod having a agitator disk fixed on one end thereof; said other end being open and defining a mouth, said mouth being located axially above said spout of said vessel, said agitator axially displaceable such that said agitator disk can mix said bone cement components;

providing a tightening rod within said tubular rod so as to seal vessel from said atmosphere before said liquid component is introduced into said vessel;

introducing said liquid component into said interior of said vessel near said vessel bottom;

re-inserting said sealing rod within said tubular rod, thereby sealing said vessel from said atmosphere;

axially displacing said agitator so as to mix said liquid and powder components under vacuum, without allowing harmful emissions to escape said mixing vessel.--

--15. The method of claim 13, wherein said container providing a container which has an open interior for receiving a glass ampoule and a threadable cap for pushing downwards on said ampoule, said interior including a means for breaking said ampoule when said cap pushes on said ampoule thereby allowing said container to feed liquid into said vessel.--

--16. The method of claim 14 further comprising the step of placing said container in said mouth of said tubular rod.--

--17. The method of claim 14 further comprising the step of providing a hole in said container wall and connecting a tube between said container and vessel in order to feed said liquid through said tube to said container bottom.--

--18. The method of claim 13 wherein said container is a plastic bag containing said liquid and said container is provided with a tube that connects into said container wall in order to feed said liquid into said vessel at said bottom.

Abstract

A method and an arrangement for successively feeding batches into a mixing vessel under partial vacuum for the preparation of bone cement. The arrangement includes an inner container communicating with the atmosphere and with the mixing vessel, which container is so arranged as to enclose a glass ampoule containing a liquid bone cement component and, on the other hand, a device for opening the ampoule so that its contents can be sucked into the mxing vessle under partial vacuum. An outer container encloses the inner container at least partially, and is arranged to communicate with the mixing vessel. The inner container, and the outer container define a space filled with a proportional quantity of a second bone cement component, which is in powder form. The inner container is capable of displacement relative to the outer container between a first position, in which sections of the inner container prevent communication between the mixing vessel and the atmosphere, and a second position, in which communication between both the mixing vessel and the atmosphere is open, so that the powdered bone cement component can be sucked into the mixing chamber under vacuum. The feeding sequence of the bone cement components is arbitrary.

FIG 1

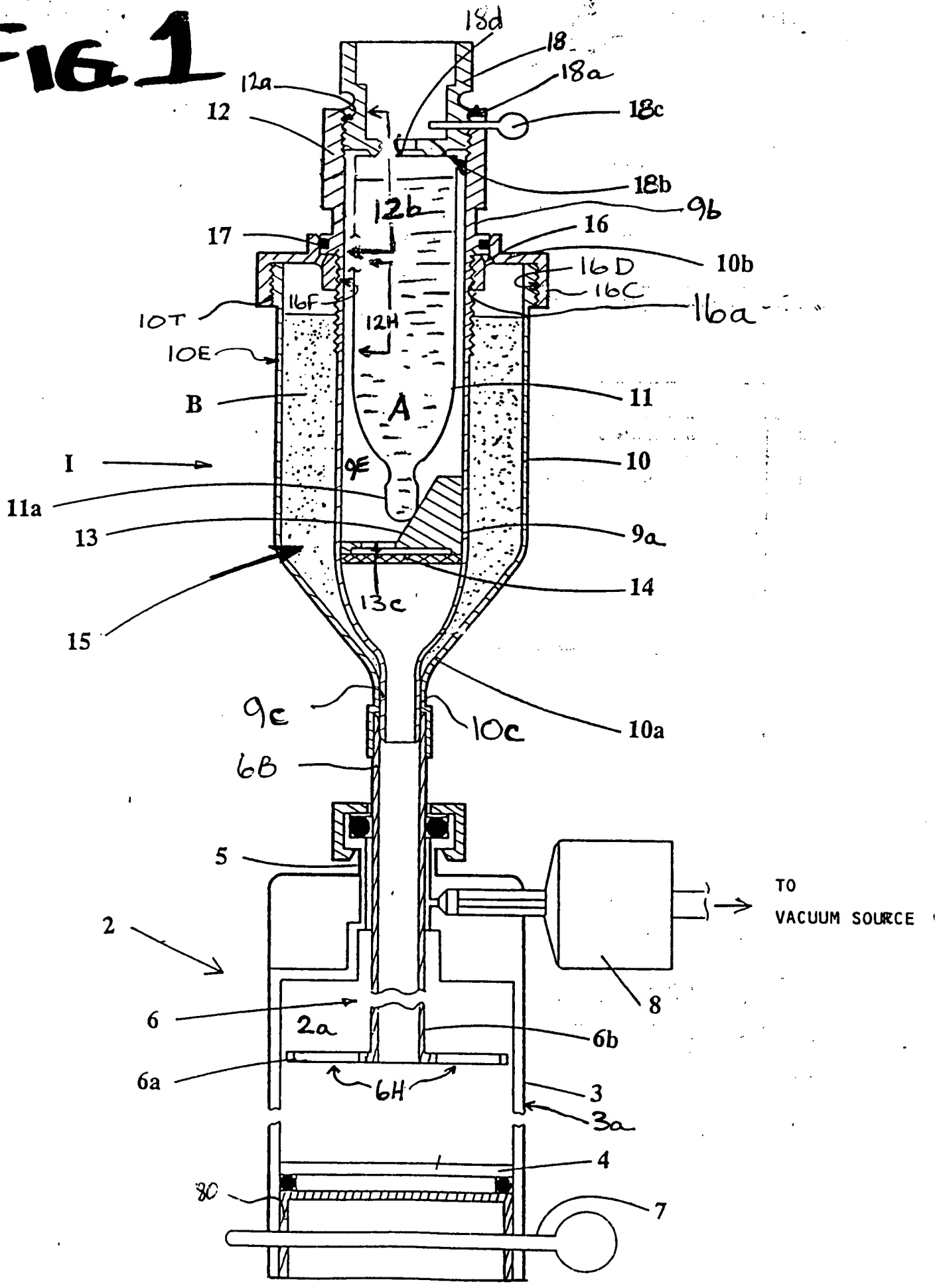
18d
18
18a
18c
12a
12
18b
12b
9b
17
16
16D
10b
16C
16a
16F
10T
12H
10E
A
B
11
I
9E
10
11a
13
9a
14
13c
15
9c
10C
10a
6B
5
TO
VACUUM SOURCE
2
8
6
2a
6b
6a
6H
3
3a
4
80
7

FIG 2

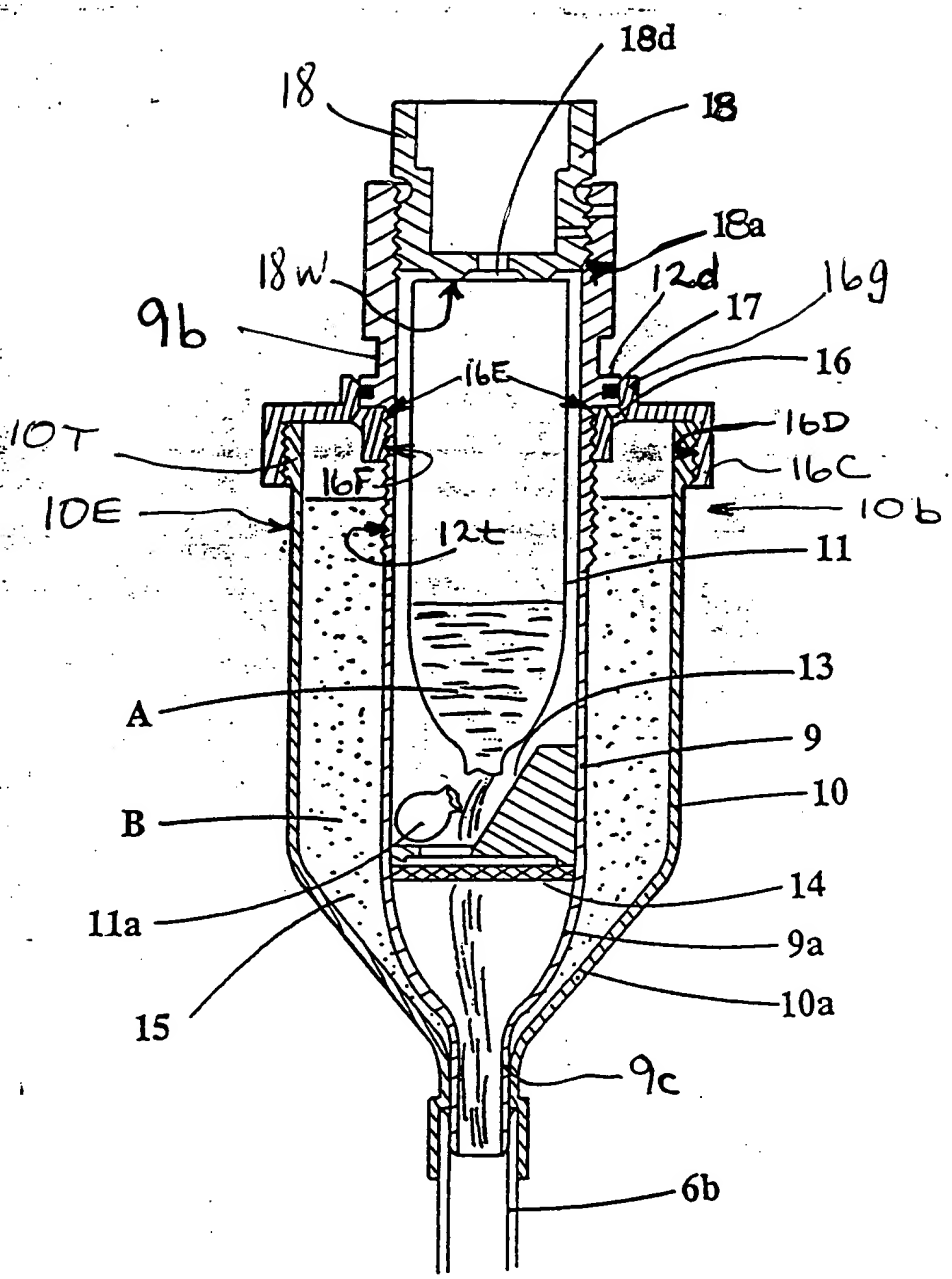
18d
18
18
18a
18w
12d
16g
9b
17
16
16E
10T
16D
16F
16C
10E
10b
12t
11
13
A
9
B
10
14
11a
9a
10a
15
9c
6b

FIG 3

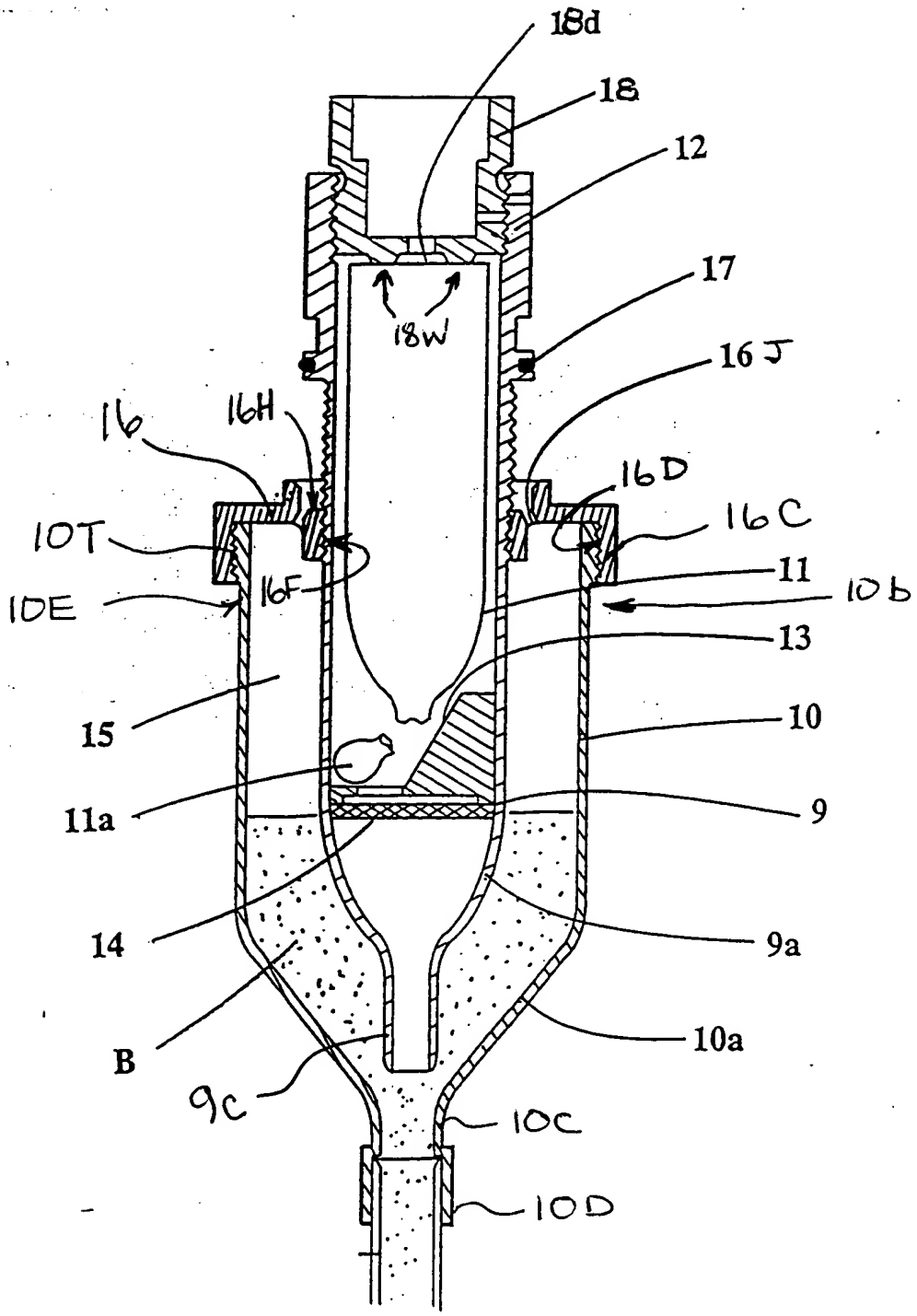
18d
18
12
17
18W
16J
16
16H
16D
16C
10T
16F
11
10b
10E
13
15
10
11a
9
14
9a
10a
B
9c
10C
10D

FIG 4

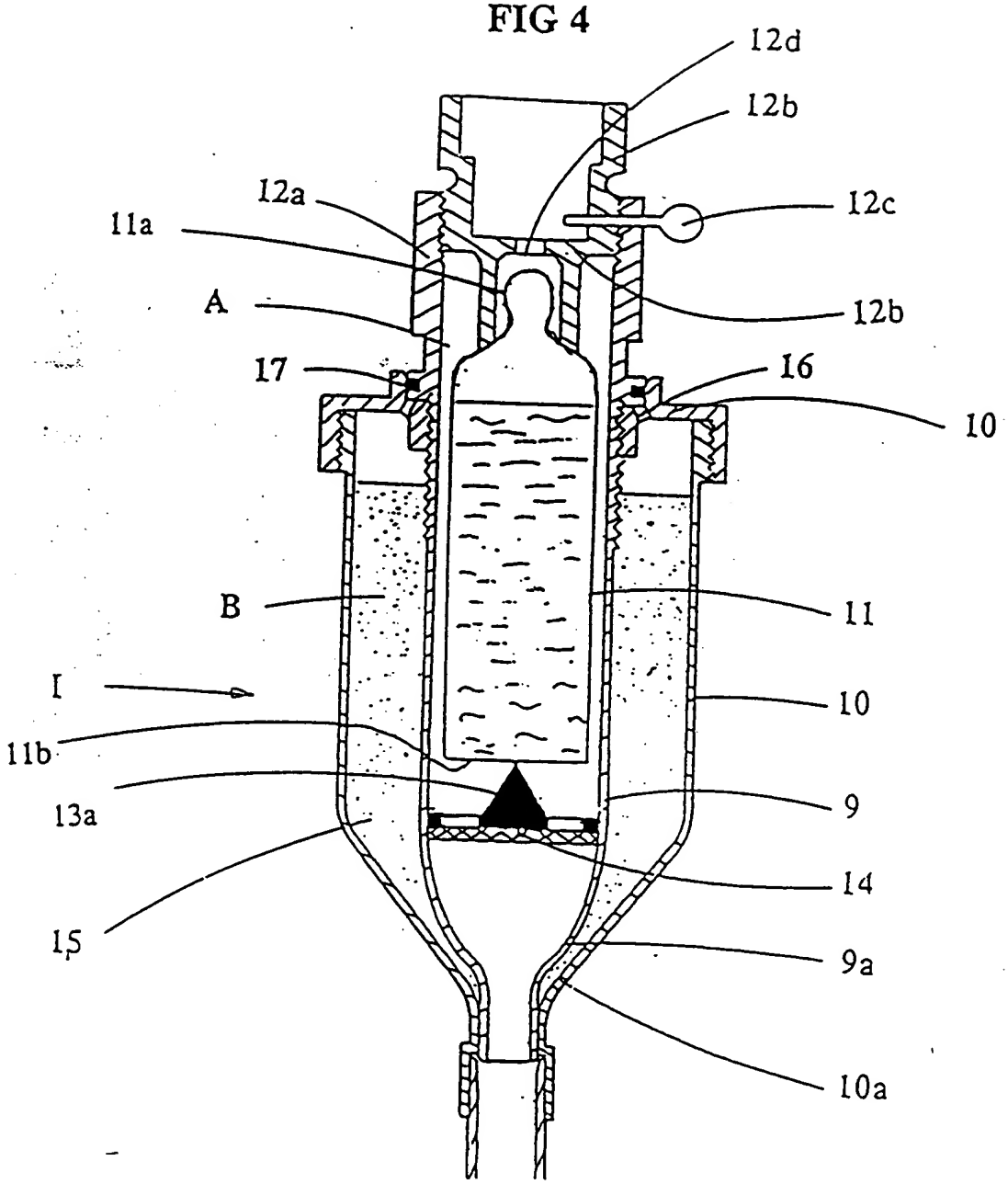

FIG 5

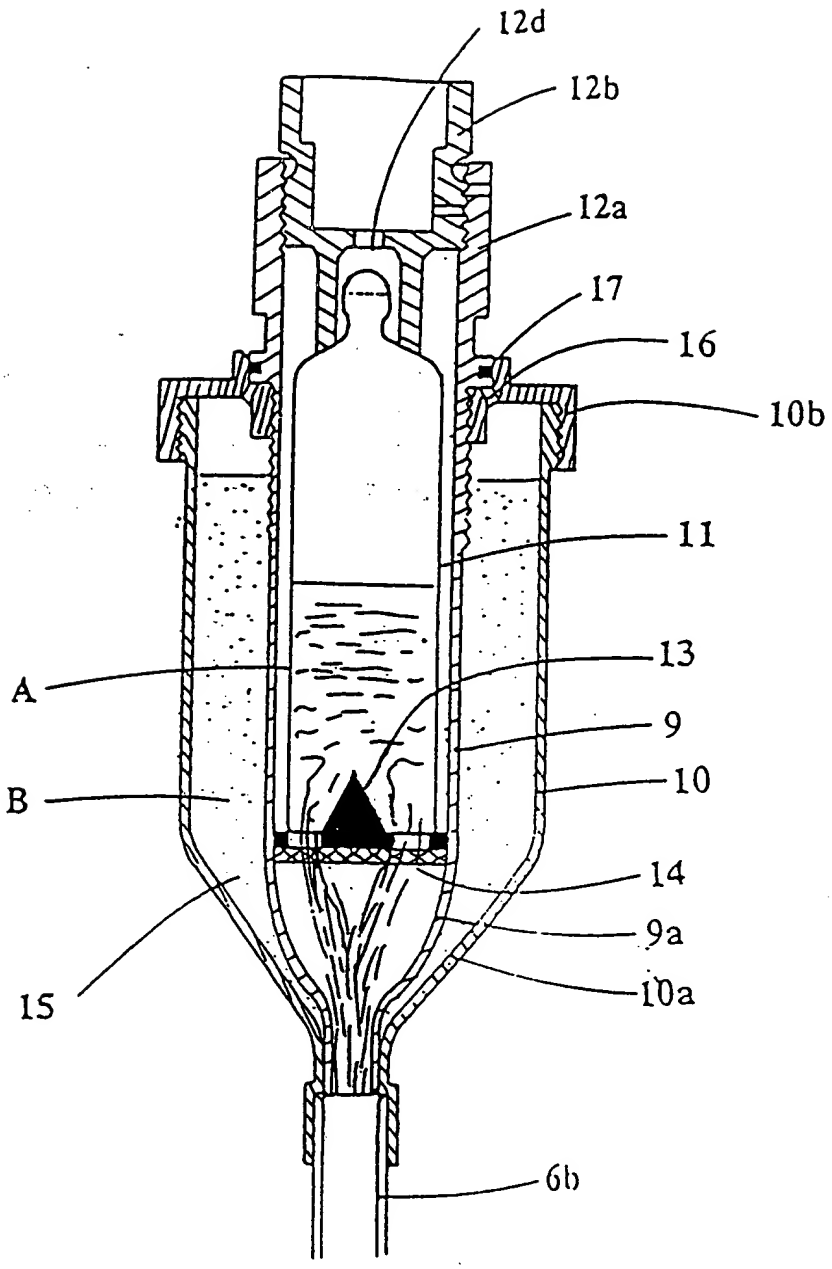

FIG 6

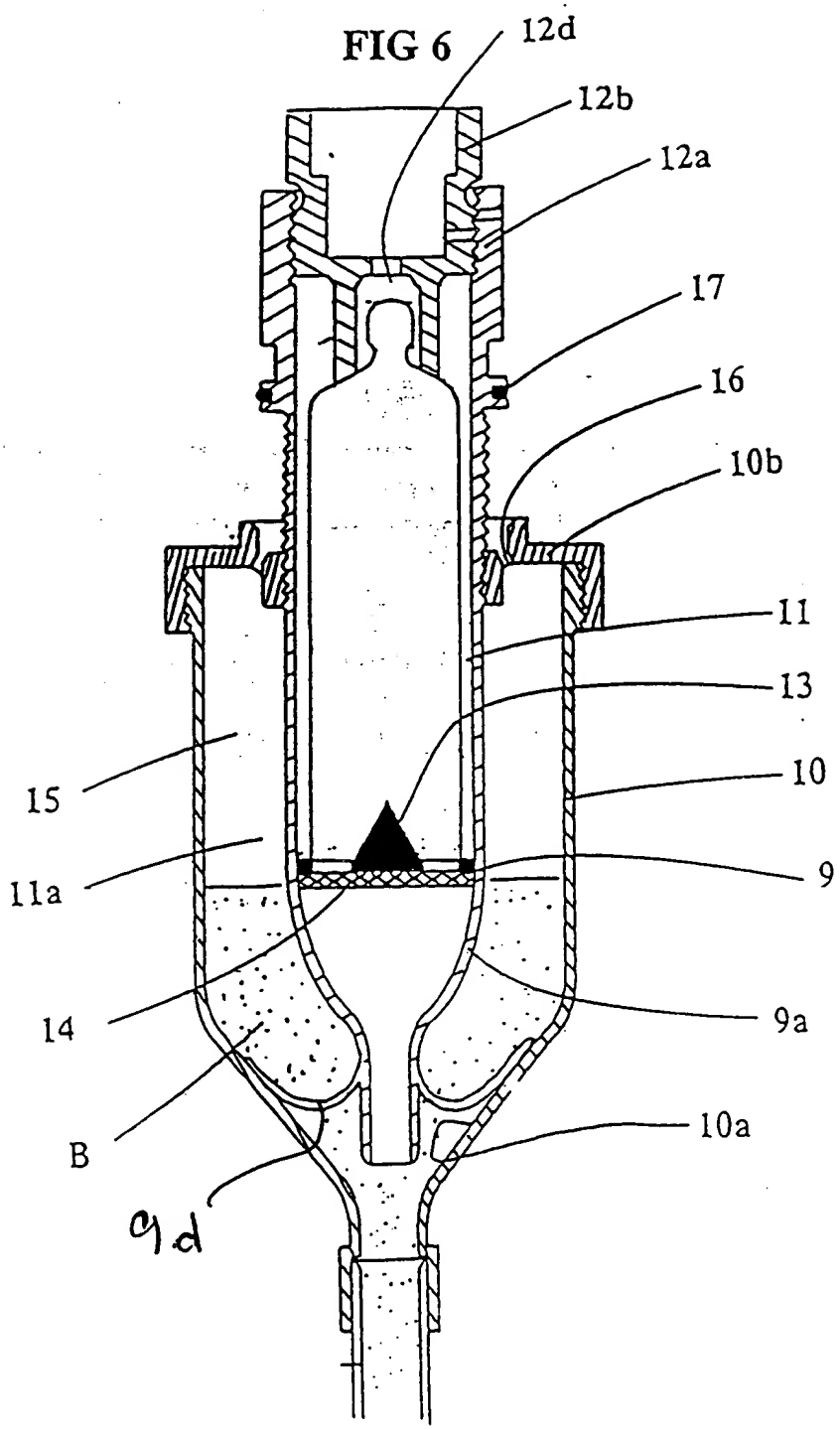

FIGURE 8

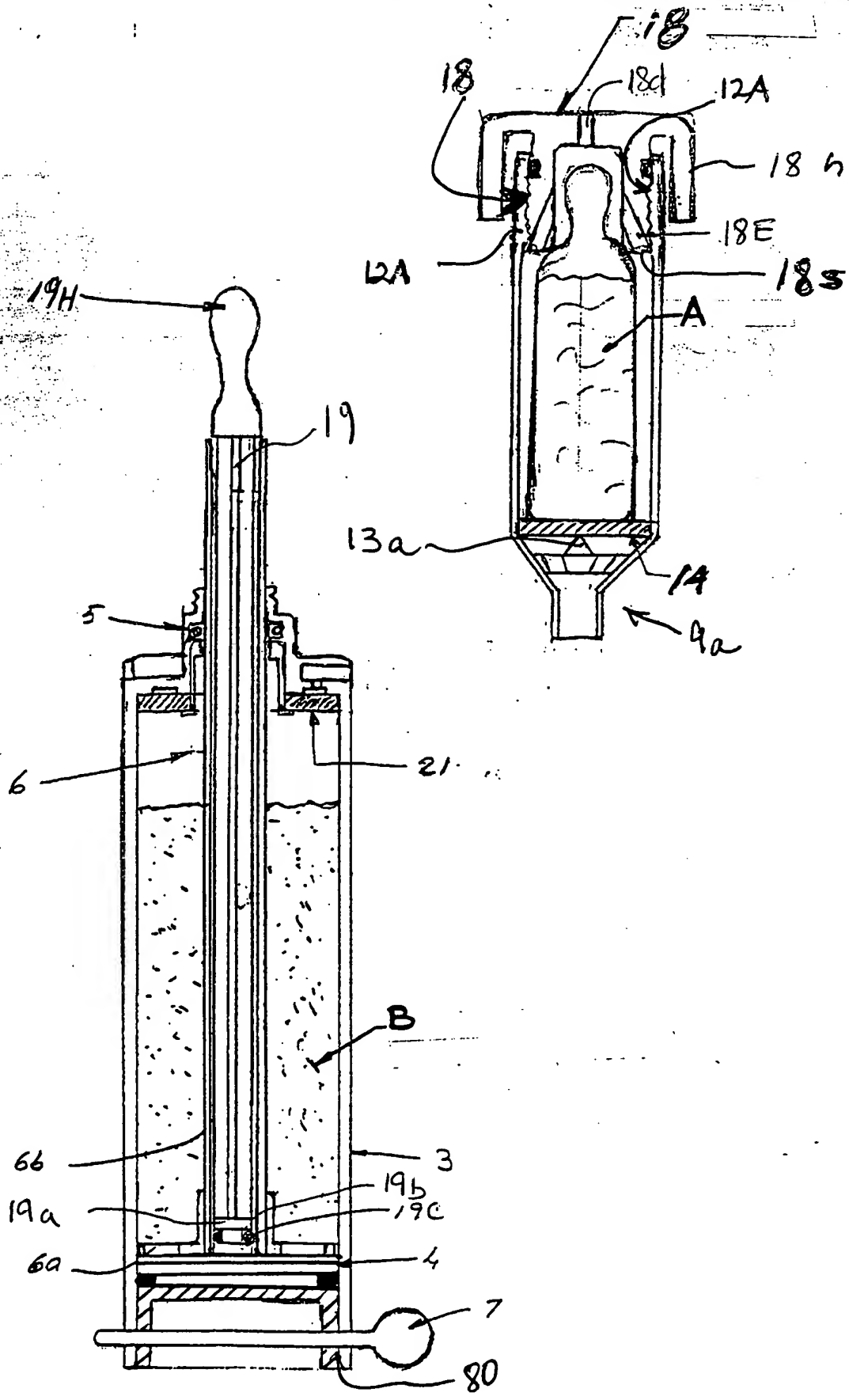

FIG. 7

FIGURE 9

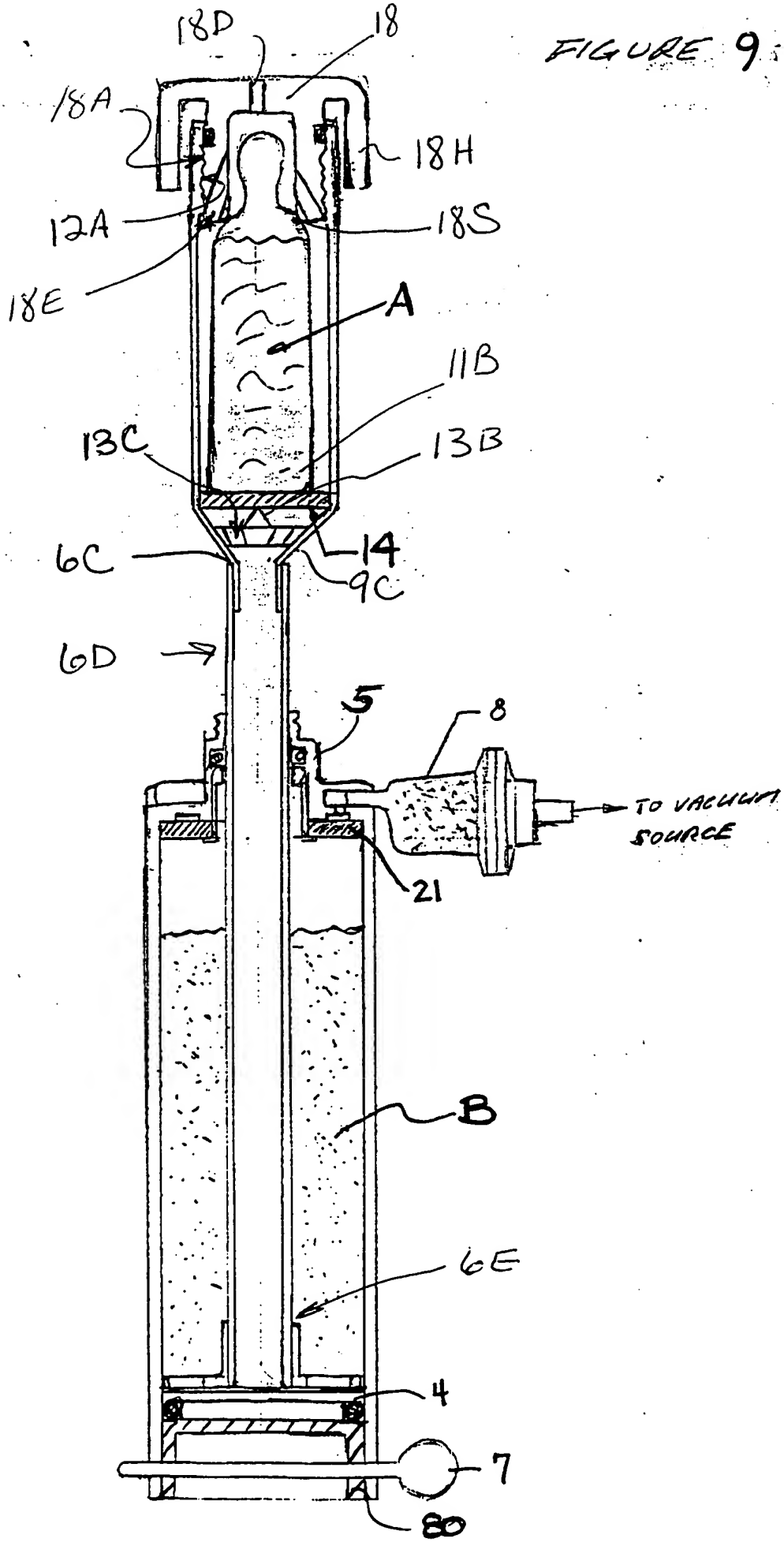

FIGURE 10

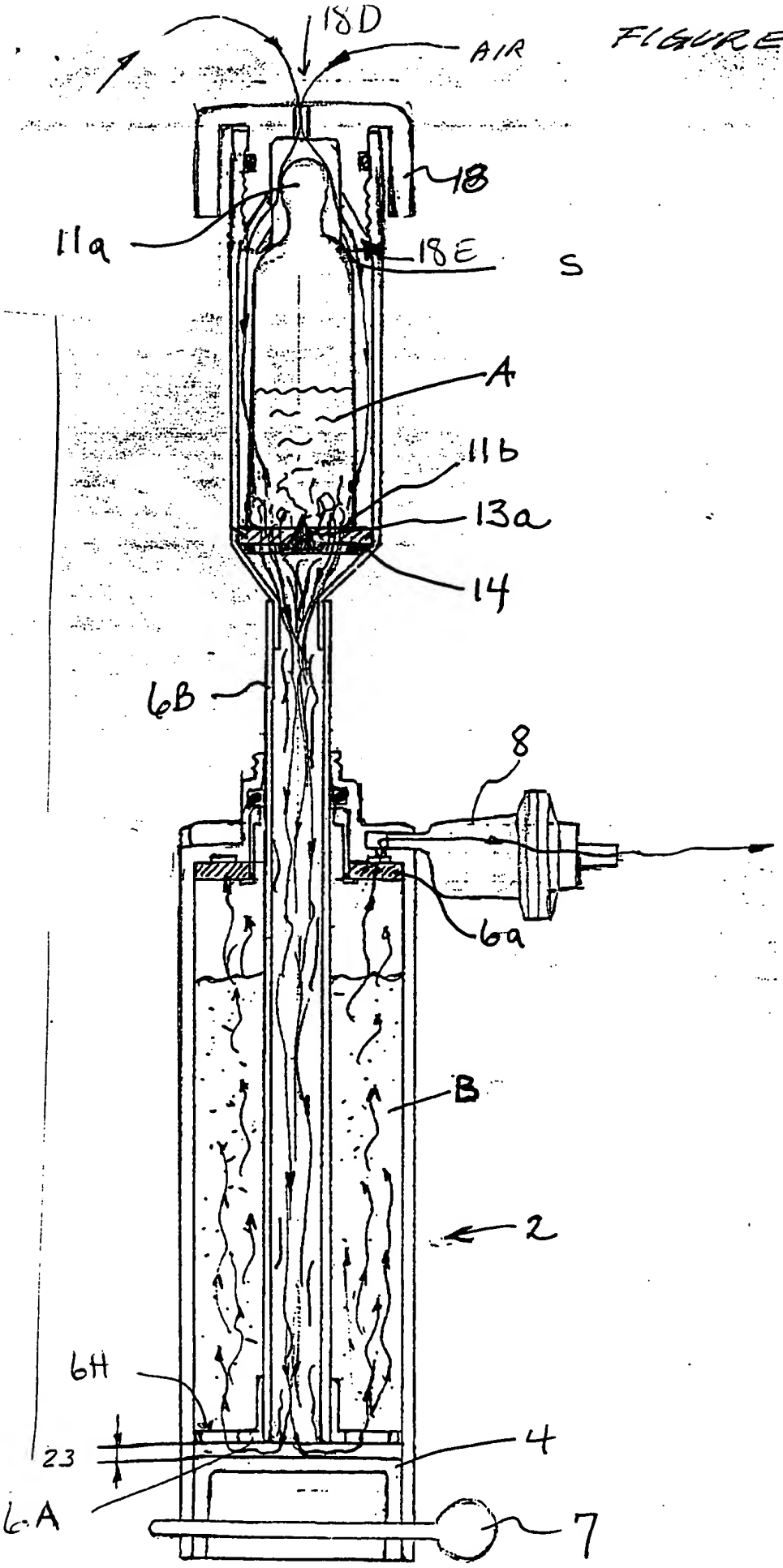

FIGURE 11

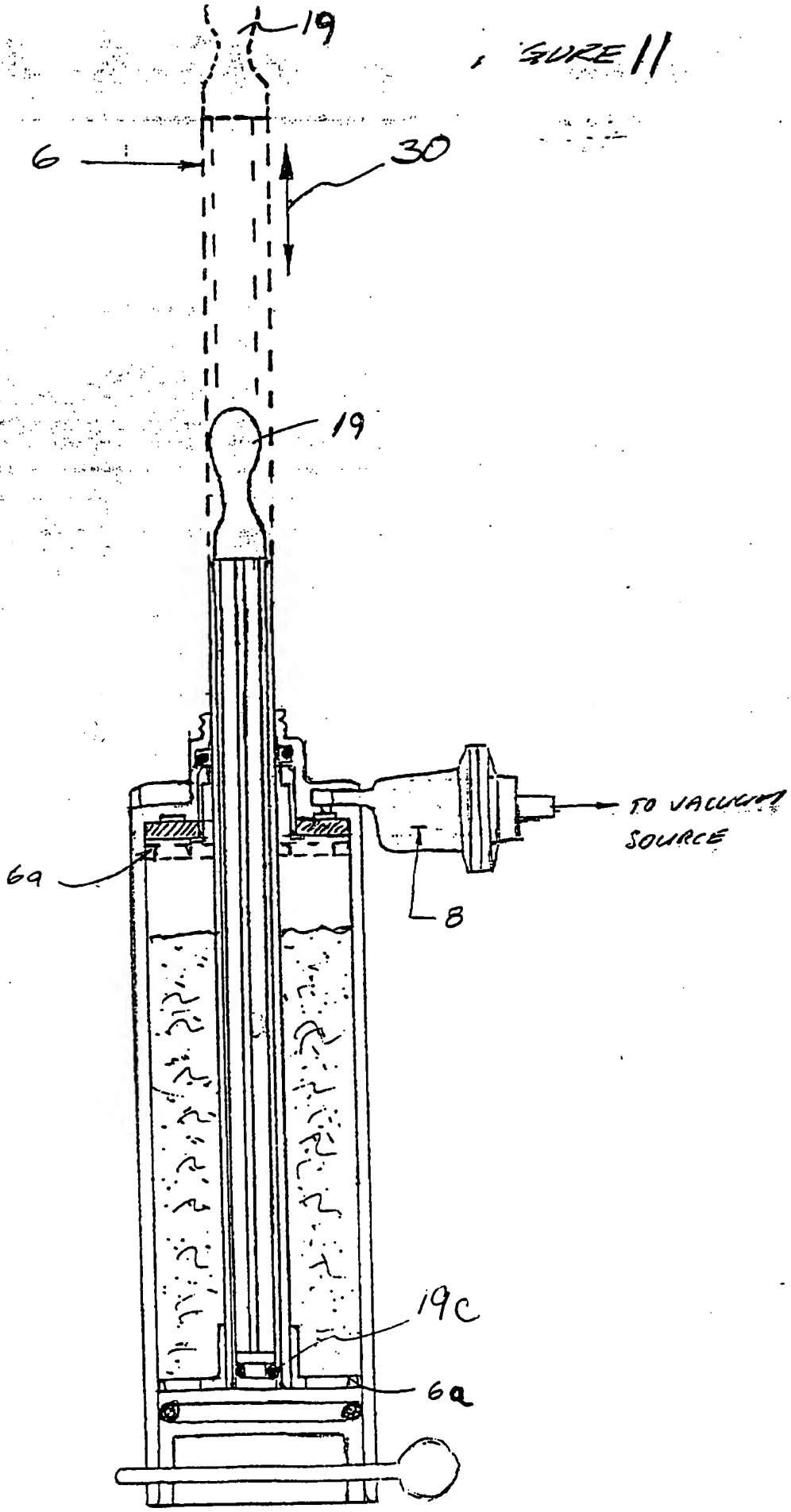

FIGURE 12

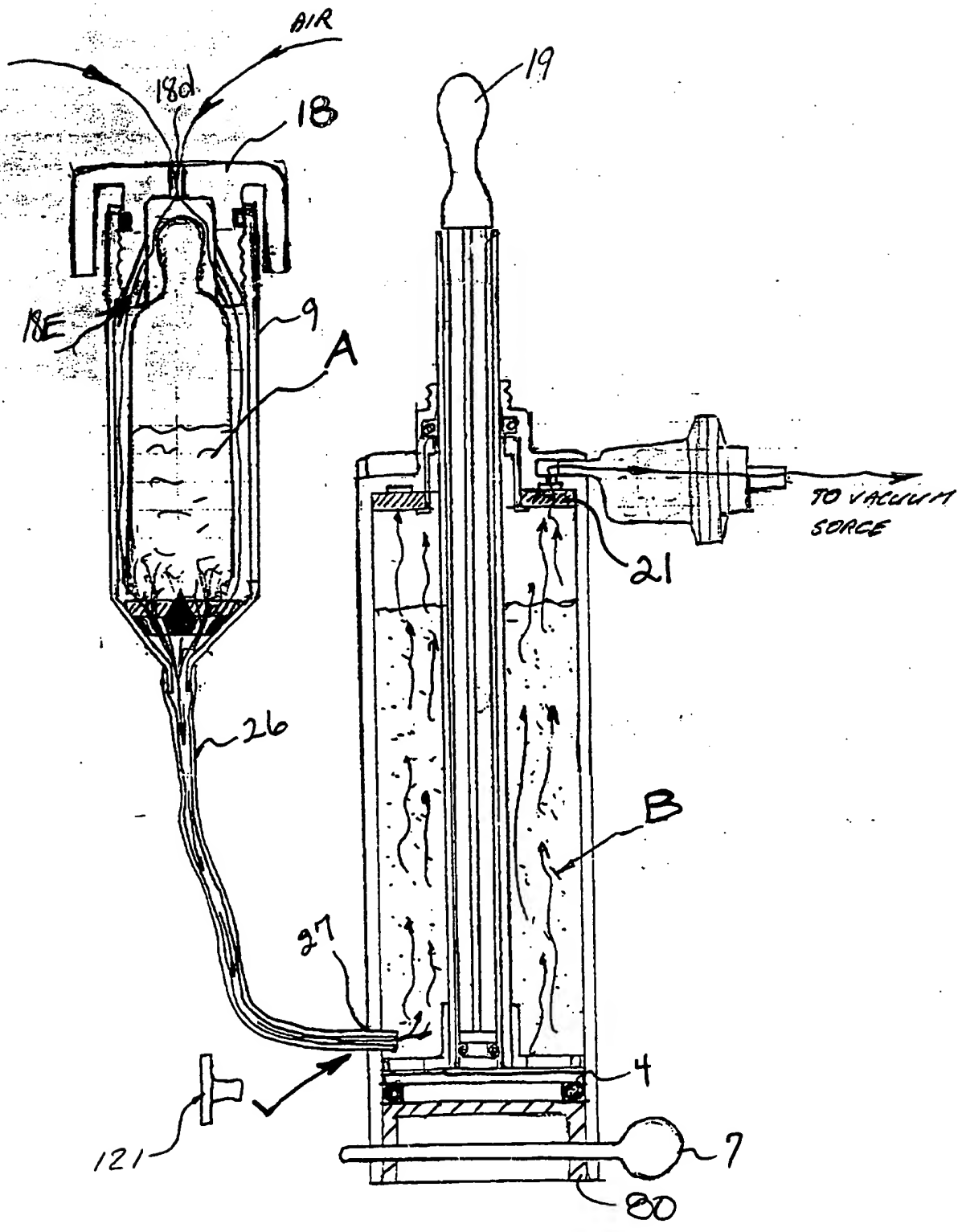

FIG. 13